K030663

MAY 2 9 2003

EXHIBIT D

510(k) Summary

Submitted by: Daniel J. Manelli
Manelli, Denison & Selter, P.L.L.C.
2000 Street, NW (Suite 700)
Washington, DC 20036
Telephone: 202-261-1000
Facsimile: 202-887-0336

On behalf of Tokuyama America, Inc.
510(k) Submission: Tokuyama SOFRELINING TOUGH
February 28, 2003

The product is a denture relining resin material for use in relining the tissue contact surface of dentures (21 CFR 872.3760)

The product is for luse only by dental practitioners; it is not intended for over-the-counter (OTC) use. It contains materials that are common in dental use and pose no health hazard when used according to directions. It is substantially equivalent to various marketed denture relining products, including the following:

Tokuyama Softrelininer (K982537)
Tokuyama Soft Relining (K953589)
GC Reline (K990736)
Coe Soft (K940566)

The Use of the product is contra-indicated for patients who are sensitive to silicone based products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2003

Tokuyama Dental Corporation
C/O Mr. Daniel J. Manelli
Manelli, Denison & Selter, P.L.L.C.
2000 M Street, NW, 7th Floor
Washington, D.C. 20036-3307

Re: K030663
Trade/Device Name: Tokuyama SOFRELINER TOUGH
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: February 28, 2003
Received: March 3, 2003

Dear Mr. Manelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

510(k) Number (if known): K030663

Device Name: Tokuyama SOFRELINER TOUGH

Indications For Use:

For use as a denture reliner

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Robert S Betz DDS for Dr K. Mabry

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030663